

REMARKS:

Upon entry of this Amendment, Claims 1, 2, 4, 6 to 12, and 14 will be pending.

I. Status of Prosecution

This application was finally rejected in the Final Action mailed May 28, 2008. Applicants timely filed a Notice of Appeal on August 26, 2008. Applicants currently submit a Request for Continued Examination including this submission.

II. Claim Rejections under 35 U.S.C. § 101

The Examiner rejected claims 1, 2, 4 and 6-13 under 35 U.S.C. § 101, because the claimed invention allegedly “is not supported by either a specific or substantial asserted utility or a well established utility.” Final Action at page 2. The Examiner contends that the results of the BLASTN analysis presented by Applicants in the Information Statement submitted February 21, 2008, do not provide evidence of a well established utility or a specific, substantial and credible utility. The Examiner’s contention is based on the allegation that the correlation presented in the BLASTN analysis was to a protein appearing in a publication appearing after the date of Applicants’ disclosure and that the specification only “discloses that the SEQ ID NOs can have high homology to wheat proteins but does not teach what these wheat proteins are, how they function, or whether any homology less than 100% identity would provide for a predictable correlation” and therefore there is no benefit to the public. Final Action at pages 8-10. Applicants respectfully disagree with the rejection.

The specification as filed discloses that a BLASTX analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. *Specification* page 5, line 19 to line 28. The results of a BLASTX analysis of SEQ ID NO: 11, which accompanies this response, shows that the protein sequence encoded by SEQ ID NO: 11 has highly significant correlations with the sequence of acyl-[acyl-carrier-protein] desaturase from a variety of plants. *See, e.g.,* the Information Statement submitted herewith. Applicants respectfully submit that one of ordinary skill in the art would recognize that the BLASTX analysis demonstrates that SEQ ID NO: 11 has a specific, substantial and credible utility that is specific to it. Moreover, as U.S. Patent 5,723,595 indicates, acyl-[acyl-carrier-protein] desaturase proteins can be used to manipulate the fatty acid content of plants, and a skilled artisan would recognize that the utility of SEQ ID NO: 11 as encoding such a protein is a well established utility.

A portion of the BLASTX search comparing SEQ ID NO: 11 to SEQ ID NO: 13 of U.S. Patent 5,723,595 is provided below. That BLASTX search shows that the protein encoded by SEQ ID NO: 11 has a score of 153 and an E-Value of 3 E-37:

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>gb|AAC31059.1|I90697 Sequence 13 from patent US 5723595
gb|AAN25922.1| Sequence 2 from patent US 6426447
gb|ABH87583.1| Sequence 2 from patent US 7053267
Length=396

Score = 162 bits (411), Expect = 3e-40
Identities = 83/130 (63%), Positives = 98/130 (75%), Gaps = 6/130 (4%)
Frame = +2

Query 2 AYTKVAARVFELDPDGMVOALAAVLADKITMPGQGLMTDGRDADLFEHFSAVAQRTGVYTA 181
Sbjct 268 AYTK+ R+FE+DPDG V A A ++R KI+MP LM DGRD +LFEHFSAVAQR GVIYA 327
AYTKIVEKLFELDPDGTVLAFADMMKKKLSMFAHLMYDGRDDNLFHFSAVAQRLGVYTA

Query 182 RDYGDVMEHFVRRWKVADLGGGQLSGEGRRAGQYVCGLPKRKIRRVVEELAHDRVIKAAKEP 361
Sbjct 328 RDYADILEFLVGRWKVADLTG--LSGEGRKAQDYVCGLPPIRRIRLEERAQGR---AKEG 381

Query 362 EFARFSWVFD 391
FSW+FD
Sbjct 382 PVVPFSWIFD 391
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Therefore, in view of the foregoing, Applicants respectfully submit that SEQ ID NO: 11 has at least a specific, substantial, or credible utility and can be used in a manner that provides some immediate benefit to the public. In other words, the claimed invention meets the utility test set forth in *In re Fisher*. Thus, Applicants respectfully request that the Examiner reverse the rejection of claims 1, 2, 4 and 6-13 under 35 U.S.C. § 101.

III. Claim Rejections under 35 U.S.C. § 112, first paragraph (Enablement)

The Examiner rejected claims 1, 2, 4 and 6-13 under 35 U.S.C. § 112, first paragraph, because, allegedly, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility, “one skilled in the art clearly would not know how to use the claimed invention.” Final Action at page 6. Applicants respectfully disagree with the rejection, and submit that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. In other words, Applicants respectfully submit that since the claimed invention has specific, substantial, and credible utility, the rejection of claims 1, 2, 4 and 6-13 with respect to the enablement requirement of 35 U.S.C. § 112, first paragraph, must be reversed.

IV. Claim Rejections under 35 U.S.C. § 112, first paragraph (Written Description)

The Examiner rejected claims 2 and 8 under 35 U.S.C. § 112, first paragraph, as allegedly “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Final Action at page 10. Applicants disagree.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not “describe,” in the sense of 35 U.S.C. § 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989).

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that Applicants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). A related and equally well-established principle of patent law is that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton*, 76 F.3d at 1175 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met). For example, an adequate written description of a genus of nucleic acids may be achieved by either “a precise definition, such as by structure, formula,

chemical name, or physical properties,” *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997), or the “recitation of structural features common to the members of the genus.” *Id* at 1568-69.

A. Claim 2 Satisfies the Written Description Requirement

The Examiner takes the position that SEQ ID NO: 11 fails to satisfy the written description requirement because it provides less than a full length open reading frame and not the entire coding sequence, and the function of the larger protein encoded by SEQ ID NO: 11 is not taught in the specification. *See* Final Action at page 10. According to the Examiner, it is not clear that SEQ ID NO: 11 encodes a wheat protein and, thus, is not representative of the genus encompassed by the claim. The Examiner’s position goes beyond what is required by 35 U.S.C. § 112, first paragraph.

As stated above, an adequate written description of a genus of nucleic acids, such as those recited in claim 2, may be achieved by providing either “a precise definition, such as by structure, formula, chemical name, or physical properties,” *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997), or the “recitation of structural features common to the members of the genus.” *Id* at 1568-69. Given Applicants’ disclosure, a skilled artisan would recognize that Applicants have provided both a precise definition of the genus of nucleic acids that are encompassed by claim 2 and a structural feature common to the genus, *i.e.*, SEQ ID NO: 11. Further, as the Examiner acknowledges, SEQ ID NO: 11 was isolated from a *Triticum aestivum* cDNA library. *See* Final Action at page 10. Applicants respectfully submit that given this disclosure a skilled artisan would be able to recognize the sequence of amino acids encoded by the nucleotide sequence of SEQ ID NO: 11

and recognize where the claimed nucleic acid molecules encode a wheat protein or fragment of a wheat protein. For example, a skilled artisan could immediately envision nucleotide sequences that may be used in connection with SEQ ID NO: 11 to encode a wheat protein or a fragment of a wheat protein.¹

To the extent the Examiner argues that SEQ ID NO: 11 does not encode a protein, Applicants respectfully point out that claim 2 recites “a wheat protein or fragment of a wheat protein” and thus, the Examiner’s argument misses the point. Further, it is well-established law that use of the transitional term “comprising” properly leaves the claims “open for the inclusion of unspecified ingredients even in major amounts.” *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271 (Fed. Cir. 1986). As discussed above and evidenced by the BLAST X search, nucleic acid molecules falling within the scope of claim 2, for example, are readily identifiable and one of ordinary skill in the art can readily identify whether a particular sequence meets the claimed characteristics or not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. In light of the disclosure it would be readily ascertainable to one of skill in the art which of the claimed nucleic acid molecules encode a wheat protein or fragment of a wheat protein.

¹ The Examiner contends that “[i]t is not clear which structural aspects of SEQ ID NO: 11, distinguish it from encoding ‘non wheat’ proteins.” Final Action at page 15. Applicants respectfully submit that, as the nucleic acid sequence of SEQ ID NO: 11 is isolated from the wheat library (as acknowledged by the Examiner), the protein product translated from SEQ ID NO: 11 would be a wheat protein or a fragment of a wheat protein.

To the extent the Examiner maintains the position presented in the Office Action of November 21, 2007 at page 19 that the “genus of nucleic acids claimed is large and variable...”, Applicants maintain that such an assertion is not a proper basis to reject claim 2 under 35 U.S.C. § 112. *See, e.g., Johnson Worldwide Assoc., Inc. V. Zebeo Corp.*, 175 F. 3d 985, 993 (Fed. Cir. 1999) (holding the patent disclosure “provide[d] ample support for the breadth of the term ‘heading’ ” to satisfy the written description requirement.) As previously stated, all Applicants must do in this case to satisfy the written description requirement under the test set forth in *Eli Lilly and Co.* is to provide either a precise definition of the genus of nucleic acids that are encompassed by the claims, or a common structural feature of the claimed nucleic acid molecules that distinguishes members of the claimed genus of nucleic acid molecules from non-members of the claimed genus. *Eli Lilly and Co.*, 119 F.3d at 1568-69. Applicants have met that burden here.

B. Claim 8 Satisfies the Written Description Requirement

The Examiner rejects claim 8 on the basis that it encompasses “sequences which possess variations with regard to the sequence of SEQ ID NO: 11 such as allelic variants and mutants.” Final Action at page 11. The Examiner also alleges that the specification does not disclose single nucleotide polymorphisms of SEQ ID NO: 11 and therefore the specification “fails to describe the necessary structural attributes that distinguishes [sic] members of the subgenus of claim 8 from non members.” *Id.* at 15. Applicants respectfully disagree with the Examiner’s position.

As stated above, an adequate written description of a genus of nucleic acids, such as those recited in claim 8, may be achieved by either “a precise definition, such as by structure,

formula, chemical name, or physical properties,” *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997), or the “recitation of structural features common to the members of the genus.” *Id* at 1568-69. In the instant case, Applicants respectfully submit that, having provided the sequence of SEQ ID NO: 11, they have provided a precise definition and a structural feature common to the nucleic acid molecules encompassed by claim 8. Applicants further submit that an ordinary artisan would be able to distinguish a single nucleotide polymorphism present in SEQ ID NO: 11, or a portion thereof by direct comparison of a nucleic acid sequence with the sequence of claim 8. In addition, single nucleotide polymorphisms can be identified, for example, by the methods described in Applicants’ specification at pages 22-23, or by any other means known in the art.

In view of the foregoing, Applicants respectfully submit the specification provides an adequate written description of the subject matter of claims 2 and 8, as it conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that Applicants were in possession of the claimed nucleic acid molecules.

V. Claim Rejections under 35 U.S.C. § 102:

The Examiner rejects claim 13 as being anticipated by:

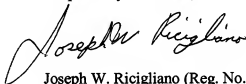
- a) EST accession number AW566142;
- b) EST accession number AI677542;
- c) Cahoon *et al.* (US Patent 6,762,345);
- d) Genbank Accession Number AF020203; and
- e) the 1998/1999 NEB Catalog.

Applicants respectfully disagree with the Examiner, however, in order to advance prosecution Applicants have cancelled claim 13 without prejudice toward pursuing the subject matter underlying claim 13 in one or more continuing applications.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Joseph W. Ricigiano".

Joseph W. Ricigiano (Reg. No. 48,511)
Holly Logue Prutz (Reg. No. 47,755)
David R. Marsh (Reg. No. 41,408)

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Arnold & Porter LLP
555 Twelfth Street, N.W.
Attn: IP Docketing
Washington, DC 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile